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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/354,450	12/12/1994	GARY K. MICHELSON	P10936V	3041

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MARTIN & FERRARO, LLP
1557 LAKE O'PINES STREET, NE
HARTVILLE, OH 44632

EXAMINER	
DEMILLE, DANTON D	
ART UNIT	**PAPER NUMBER**
3764	25

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	08/354,450	MICHELSON, GARY K.
	Examiner	Art Unit
	Danton DeMille	3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-300* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-300* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The amendment filed 07 January 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in the claims it is recited that a) said flexible member being at least in part curved b) said flexible member is deformable to have an at least in part concave shape c) said flexible member has a greater surface area to mass ratio than said shaft d) said flexible member has a smaller mass than the mass of said shaft e) said flexible projections are oriented in at least two arrays along the mid-longitudinal axis of said shaft f) said flexible projections are oriented in at least four arrays along the mid-longitudinal axis of said shaft g) at least two of said flexible projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft h) said rivet has a length of approximately 10 mm i) at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees j) the outer perimeter remains substantially in a single plane when moving relative to said shaft k) at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft l) at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

There appears to be no support in the specification for the above noted language or the criticality why this is now being claimed.

Claims 29-300 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not adequately described as set forth in the above objection to the specification.

Claim Rejections - 35 USC § 112

Claims 29-300 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There doesn't appear to be any support in the specification for the language noted above in the objection to the specification. For example, it is not clear how much weight can be given the language that the flexible projections are oriented in at least two arrays along the mid-longitudinal axis of the shaft when there is no disclosure for such structure. Applicant is using the language "along the mid-longitudinal axis of the shaft to mean along the length of the shaft. As understood there are no plural arrays of projections that run along the length of the shaft. There are plural arrays that run "around" the mid-longitudinal axis of the shaft but not "along" the shaft.

There also doesn't appear to be support for at least two of the flexible projections to extend in the same plane transverse to the axis of the shaft. As understood the projections extend

at an angle "slightly sloped away from the projection head 14" (paragraph spanning pages 5-6 of this disclosure). If the projections extend at an angle to the shaft then it would be impossible for an adjacent projection to extend in the same plane.

The rivet is also not disclosed as being approximately 10 mm in length. It is disclosed as being approximately 8 mm in length.

The flexible member is also not disclosed as being part curved or part concave or at an angle not perpendicular to the longitudinal axis of the shaft.

To any extent the claims are understood and appear to be supported by a clear an complete disclosure the following appears to be appropriate.

Claim Rejections - 35 USC § 103

Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren.

Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of flexible projections extending from said shaft and the flexible member at the other end. He also discloses that the rivet is made of biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion (column 6, lines 1-6). Due to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that rivet of Warren would comprehend the claimed resilient characteristic at least

to some extent. It is not clear exactly how the claimed rivet is different from Warren's rivet. The only difference between the claims and Warren's device is that the claims recite that the flexible head member deforms when it is pounded into place. Inherently any head member made of a polymeric material when pounded into place on a surface that is curved or irregular will deform at least to a certain extent. The 2.5 mm size of the polymeric rivet would also yield a degree of flexibility to the rivet. As the rivet is being forced into the bone the head will come into contact with the first portion of the bone it meets and as the rivet continues to be forced into the bone other portions of the head will then come into contact with the bone. Because different portions of the head will come into contact with the bone at different times the head will deform as one portion of the head cannot move and other portions continue to move closer to the bone. The resulting head portion will deform at least to some extent. It would appear that the fastener of Warren comprehends the claims since all of the positive structural limitations are met. The intended use of the rivet deforming in use would also appear to be comprehended by the structure of Warren.

Warren teaches "the dimensions of the fastener could be changed so as to make the fastener longer and thinner, or shorter and fatter, etc." column 6, lines 46-49. Warren goes further to state, "for other purposes (e.g., for attaching ligaments to bones in the leg region), other dimensions may be more desirable." Clearly the dimensions and relative sizes can be modified dependent on practical intended use considerations. Warren teaches that the fastener can be thinner. If the device is intended to be used in softer tissue then the thickness of the fastener can be reduced. A thinner fastener would make a more flexible fastener. Softer tissue would require the projections to be a little longer to more securely engage the softer tissue. The

specific dimensions used for a specific intended use are well within the realm of the artisan of ordinary skill. Such considerations are obvious to one of ordinary skill in the art and not a patentable distinction. This thinner fastener would then result in a head member that would flex as it is forced into contact with the bone. To any extent it is felt that the structure of Warren is not flexible enough to flex during use, it would have been obvious to modify the rivet of Warren as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough that would result in a head that flexes during implantation.

Moreover, making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art. As the skin moves over the head of the fastener the skin can become irritated. Reducing the size of the head would provide a smooth transfer surface, thereby insuring that nothing would be caught on the extending rivet head and damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation.

Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, 256-300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. in view of Warren. Bays teaches another fastener that has all of the claimed structure including being made out of the same material as the instant invention. For the same reasons as above, it is not clear how the claimed invention would define over Bays other than how it deforms during use. It would appear the rivet of Bays comprehends the claims including the flexible head member being "adapted so as to conform to the surface of the tissue in which said rivet is inserted, said flexible member being at least in part curved when said flexible member is in contact with the tissue". If the area of the bone where the rivet is

being inserted is curved then the head member would be pressed against the curved surface an deform to match the same shape at least to a certain extent. The same structure made of the same material would appear to comprehend the claimed invention.

Bays teaches the rivet is approximately 8 mm long. As noted above, the specific dimensions of the rivet are well within the realm of the artisan of ordinary skill. It would have been obvious to modify Bays to dimension the rivet to fit any specific intended use desired. To any extent it is felt that the structure of Bays is not flexible enough to flex during use, it would have been obvious to modify the rivet of Bays as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough resulting in a head that flexes during implantation as noted above.

Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Duncan, Chisholm et al. or Paravano.

There is no unobviousness to the specific shape or number of ribs on the shaft of the rivet. Both Bays and Warren teach that the specific configuration of the ribs is well within the artisan of ordinary skill. Warren teaches column 7, lines 3+ "that surgical fastener 100 might be formed with more or less ribs 135 than the three ribs shown in FIGS. 1-8. Thus, for example, a surgical fastener 100A having eight ribs 135A is shown in FIGS. 9-11." Bays teaches column 4, lines 62-64, "As few as one and more than three barb members may be provided within the scope of the present invention, so long as the barb member or members provide sufficient resistance to rearward movement of the shaft portion through the cartilaginous tissue." Duncan, Chisholm and Paravano are all cited to show different conventional alternative arrangements of ribs on the

shafts of fasteners. Duncan teaches a surgical fastener that has barbs that are spaced in plural arrays around the axis of the shaft. Chisholm and Paravano also exemplify the art of providing plural arrays of barbs or fins spaced around the axis of the shaft. It would have been obvious to one of ordinary skill in the art to further modify the prior art to arrange the ribs, fins or barbs in arrays around the axis of the shaft as taught by Duncan, Chisholm or Paravano to provide the desired level of anchorage for the fastener to hold it in place.

Claims 87, 88, 131, 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to the claims above, and further in view of Simons.

There appears to be no unobviousness to exactly how the rivet interfaces with the driving element. The driving element of the rivet merely has to drive the rivet into the bone. Warren teaches a hollow driver 600 that buts the end of the rivet to force the rivet into the hole in the bone. Bays teaches a driver that includes a shaft that mates with a passageway within the rivet. There is no unobviousness to how the driver forces the rivet into the bone. Simons teaches another equivalent way for the driver to mate with the head of the fastener. The fastener includes a generally spherical recess in the head. It would have been obvious to one of ordinary skill in the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ddd
13 March, 2004
(703) 308-3713
Fax: (703) 872-9306
danton.demille@uspto.gov

Danton DeMille
Primary Examiner
Art Unit 3764